California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Legislation and Regulation Committee Report
July 11, 2003

Andrea Zinder, Chair
Dave Fong, Member

NO ACTION

Pending Regulations

Section 1732.05 – Continuing Education
Summary: This regulation will recognize continuing education credits approved by other California health professions licensing boards.
Status: Pending review by the Office of Administrative Law (OAL)

Section 1751 – Sterile Compounding
Summary: This regulation will establish guidelines for the compounding of sterile drug products.
Status: Awaiting publication of a second 15-Day notice

Section 1775 et seq. – Citation and Fine
Summary: This regulation designates the executive officer as the issuing authority for citations and fines. The regulation also consolidates and recasts existing board regulations relating to citations and fines.
Status: Pending review by the Department of Consumer Affairs

Regulations Awaiting Notice

Section 1707.5 – Hospital Central Fill
Summary: This regulation will permit central refill operations for hospitals.
Status: Conducted informational hearing at October 2002 board meeting.

Section 1709.1 - Pharmacist-in-Charge at Two Locations
Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.
Status: Informational Hearing Required

Section 1715 – Pharmacy Self Assessment
Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.
Status: Informational Hearing Required

Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records
Summary: This regulation will make any needed changes to board regulations to conform to recent changes in law.
Status: Informational Hearing Required

Section 1717.4 – Authentication of Electronic Prescriptions
Summary: This regulation will require pharmacists to authenticate electronic prescriptions.
Status: Informational Hearing Required

Section 1784 – Wholesaling
Summary: This regulation will impose dollar volume limits on wholesale drug transfers by pharmacies, impose dollar volume limits on transfers between wholesalers, and require pedigrees for drug shipments under specified circumstances.
Status: The Enforcement Committee conducted an informational hearing on this proposal at its July 2, 2003 meeting.

Section 1793.3 – "Clerk-Typist" Ratio
Summary: This regulation will eliminate the clerk/typist ratio.
Status: Informational Hearing Required

The Committee also scheduled an informational hearing in September to begin the rulemaking process on the existing calendar of proposed rulemakings. Staff will publish draft language for each proposal in advance of the informational hearing. Subsequent to the informational hearing, the rulemaking proposals will be formally published for comment.

Pending Legislation

Senate Bill 361 (Figueroa)

This bill is the board's sunset review legislation. The bill contains the recommendations from the Joint Legislative Sunset Review Committee that require statutory changes including:

- Adoption of NAPLEX and the MPJE.
- Add two public members to the board.
- Permit non-pharmacists to be board inspectors.
- Revision of pharmacy technician qualifications.

The bill also contains the board's omnibus items for 2003.

The bill passed the Assembly Business and Professions Committee on Wednesday, July 9, 2003 on a 13-0 vote. The will next go to the Assembly Appropriations Committee. The bill has no opposition at this time and is expected to be signed by the Governor. The bill was recently amended to require periodic evaluation of the NAPLEX and designates three of the pharmacist seats on the board as follows:

- A pharmacist who is a union member.
- A chain community pharmacy representative (more than 75 stores).
- An independent community pharmacy representative (four or fewer stores).

A copy of this bill is provided for your reference in Attachment A

Status of Bills with a Board Position

AB 261 (Maddox) Increases penalties for operating a "backroom pharmacy."
Board Position: **Support**
Status: Dead

AB 746 (Matthews) Requires the board to revoke a license after a second conviction for Medi-Cal fraud.
Board Position: **Support**
Status: Senate Business and Professions Committee

AB 1363 (Berg) Establishes requirements for needle exchange programs.
Board Position: **Support**
Status: Two-year bill

AB 1460 (Nation) Permits pharmacists to perform CLIA waived tests to monitor drug therapy. Board Position: **Support**
Status: Two-year bill

SB 151 (Burton) Eliminates the triplicate requirement for Schedule II prescriptions and requires a tamper resistant prescribing pad for all controlled substance prescriptions. Adds Schedule III drugs to CURES. The full text is included for your reference as Attachment B.
Board Position: **Support**
Status: Assembly Appropriations Committee

SB 175 (Kuehl) Adds veterinary drugs to the definition of dangerous drugs.
Board Position: **Support**
Status: Assembly Appropriations Committee

SB 393 (Aanestad) Permits "tech check tech" in hospitals.
Board Position: **Support if Amended**
Status: Two-year bill

SB 490 (Alpert) Establishes a statewide protocol for pharmacists dispensing emergency contraception.
Board Position: **Support**
Status: Assembly Appropriations Committee

SB 506 (Sher) Requires the board to track wholesale distribution of antibiotic drugs.
Board Position: **Oppose**

Status: Two-year bill

SB 545 (Speier) Limits the nature of the consultation and the fee that may be charged by pharmacists dispensing emergency contraception. The author accepted amendments to resolve the boards opposition. These amendments include restoring the training requirement and eliminating restrictions on the consultation provided by the pharmacist.
Board Position: **Neutral**
Status: Assembly Appropriations Committee

SB 774 (Vasconcellos) Eliminates the prescription requirement for hypodermic needles and syringes.
Board Position: **Support**
Status: Assembly Health Committee

Bills of Interest

AB 57 (Bates) Places MDMA into Schedule II.
Status: Assembly Inactive File

AB 186 (Correa) Makes technical changes to the Pharmacy Law relating to optometrists.
Status: Senate Business and Professions Committee

AB 521 (Diaz) Requires pharmacists to notify patients of harmful drug interactions.
Status: Two-year bill.

AB 1196 (Montanez) Permits nurse practitioners to order Schedule II drugs.
Status: Senate Appropriations Committee

SB 292 (Speier) Requires prescription labels to have a description of the drug.
Status: Assembly Appropriations Committee

Quarterly Status Report on Committee Goals for 2002-03

For your information, an update of the Committee's progress in accomplishing its strategic objectives is attached to this report (Attachment C).

Meeting Summary for July 11, 2003

For your information the minutes from the March 27, 2003 meeting of the Legislation and Regulation Committee meeting is attached to this report (Attachment D). The committee scheduled its next meeting for June 25, 2003 at 9:00 a.m.

Attachment A

AMENDED IN ASSEMBLY JULY 7, 2003

AMENDED IN ASSEMBLY JUNE 23, 2003

AMENDED IN SENATE APRIL 21, 2003

SENATE BILL No. 361

Introduced by Senator Figueroa
(Coauthors: Senators Aanestad and Vincent)
(Coauthors: Assembly Members Correa, Nation, and Runner)

February 19, 2003

An act to amend Sections 4001, 4002, 4003, 4008, 4062, 4200, 4202, 4312, 4400, and 4403 of, and to add Sections 4083, 4106, 4200.2, 4200.3, 4200.4, 4314, and 4315 to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 361, as amended, Figueroa. Pharmacy: administration and enforcement.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy within the Department of Consumer Affairs. Under existing law, the board is authorized to appoint an executive director to exercise the powers and perform the duties delegated by the board. The law makes these provisions inoperative on July 1, 2004, and repeals them on January 1, 2005. Under existing law, the board consists of 11 members, 2 of whom are public members appointed by the Governor.

This bill would delete these inoperative and repeal dates and would extend the operation of these provisions to make them inoperative on July 1, 2008, and repeal them on January 1, 2009. The bill would also increase the board membership to 13 by adding 2 more public members appointed by the Governor ~~and~~. *The bill* would also specify that one of

the pharmacist appointees be a member of a labor union representing pharmacists*, that one practice in an independent community pharmacy setting, and that another practice in a chain community pharmacy setting*.

Existing law authorizes the board to employ inspectors of pharmacy. These inspectors are required to be pharmacists if their principal duties are either inspecting or investigating pharmacies or pharmacists or supervising other inspectors of pharmacy.

This bill would delete the requirement that certain inspectors of pharmacy must be pharmacists. The bill would authorize inspectors to issue a written order of correction and the executive officer, or his or her designee, to issue a letter of admonishment, directing a licensee to comply with the Pharmacy Law or related regulations. The bill would require an order of correction or a letter of admonishment to contain certain information, including the process for a licensee to contest the order or letter. The bill would require a licensee to have readily available on the pharmacy premises a copy of any order of correction or letter of admonishment issued against it in the prior 3 years, and a related corrective plan of action. The bill would provide that an order of correction would not be a public record, except as specified.

This bill would authorize the board to issue a citation for a violation of the Pharmacy Law or related regulations, with a fine of up to $2,500 and an order of abatement, which may require a person to demonstrate how future compliance will be accomplished.

Existing law sets forth certain educational, training, and examination requirements that an applicant for a pharmacist license must meet.

This bill would revise the examination requirements, as specified, and would require the board to develop a Multi-State Pharmacy Jurisprudence Examination for California that meets certain guidelines and to review the examination process. The bill would prohibit an applicant who failed the national examination from retaking it for a designated time period.

Existing law requires an applicant for a pharmacy technician certification to meet certain education requirements.

This bill would revise those education requirements.

The Pharmacy Law makes a violation of its provisions a crime.

Because this bill would create new requirements for licensees under that law, the violation of which is a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, ~~a~~ *an independent* community pharmacy, *a chain community pharmacy,* and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. ~~This member shall be appointed to the board upon the first expiration of a term of a pharmacist appointee that occurs on or after January 1, 2004.~~ *For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.*

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 2. Section 4002 of the Business and Professions Code is amended to read:

4002. (a) The board shall elect a president, a vice president, and a treasurer. The officers of the board shall be elected by a majority of the membership of the board.

(b) The principal office of the board shall be located in Sacramento. The board shall hold a meeting at least once in every four months. Seven members of the board constitute a quorum.

SEC. 3. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 4. Section 4008 of the Business and Professions Code is amended to read:

4008. (a) Except as provided by Section 159.5, the board may employ inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the

person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

SEC. 5. Section 4062 of the Business and Professions Code is amended to read:

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

SEC. 6. Section 4083 is added to the Business and Professions Code, to read:

4083. (a) An inspector may issue an order of correction to a licensee directing the licensee to comply with this chapter or regulations adopted pursuant to this chapter.

(b) The order of correction shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statute or regulations violated.

(c) The order of correction shall inform the licensee that within 30 days of service of the order of correction, the licensee may do either of the following:

(1) Submit a written request for an office conference with the board's executive officer to contest the order of correction.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the licensee's legal counsel or authorized representative may accompany the licensee to the office conference.

(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the order of correction.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the order of correction. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the order of correction.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether

or not there was a prejudicial abuse of discretion in the issuance of the order of correction.

(2) Comply with the order of correction and submit a written corrective action plan to the inspector documenting compliance. If an office conference is not requested pursuant to this section, compliance with the order of correction shall not constitute an admission of the violation noted in the order of correction.

(d) The order of correction shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date of issuance of the order of correction.

(f) Nothing in this section shall in any way limit the board's authority or ability to do any of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Issue a letter of admonishment pursuant to Section 4315.

(3) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

(g) Unless a writ of mandate is filed, a citation issued, a letter of admonishment issued, or a disciplinary proceeding instituted, an order of correction shall not be considered a public record and shall not be disclosed pursuant to a request under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

SEC. 7. Section 4106 is added to the Business and Professions Code, to read:

4106. For purposes of license verification, a person may rely upon a printout from the board's Internet Web site that includes the issuance and expiration dates of any license issued by the board.

SEC. 8. Section 4200 of the Business and Professions Code is amended to read:

4200. (a) The board shall license as a pharmacist, and issue a certificate to, any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the applicant has received a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has had 1,500 hours of pharmaceutical experience in accordance with regulations adopted by the board.

(A) ''Pharmaceutical experience,'' constitutes service and experience in a pharmacy under the personal supervision of a pharmacist, and consists of service and experience predominantly related to the selling of drugs, compounding physician's prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes.

(B) To be credited to the total number of hours required by this subdivision, this experience shall have been obtained in pharmacies and under conditions set forth by rule or regulation of the board.

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

SEC. 9. Section 4200.2 is added to the Business and Professions Code, to read:

4200.2. When developing the Multi-State Pharmacy Jurisprudence Examination for California, the board shall include all of the following:

(a) Examination items to demonstrate the candidate's proficiency in patient communication skills.

(b) Aspects of contemporary standards of practice for pharmacists in California, including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the North American Pharmacy Licensure Examination.

SEC. 10. Section 4200.3 is added to the Business and Professions Code, to read:

4200.3. (a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Examination Resources of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. *If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.*

(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) The board shall work with the Office of Examination Resources or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail

rates before utilization of the North American Pharmacist ~~LIcensure~~ *Licensure* Examination.

(f) The board shall report to the Joint Legislative Sunset Review Committee and the department as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 11. Section 4200.4 is added to the Business and Professions Code, to read:

4200.4. An applicant who fails the national examination may not retake the examination for at least 90 days or for a period established by regulations adopted by the board in consultation with the Office of Examination Resources of the department.

SEC. 12. Section 4202 of the Business and Professions Code is amended to read:

4202. (a) An applicant for registration as a pharmacy technician shall be issued a certificate of registration if he or she is a high school graduate or possesses a general education development equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education or a school of pharmacy recognized by the board. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician certificate of registration must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the registration of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for registration as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of registration, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a registration issued pursuant to this section on any ground specified in Section 4301.

SEC. 13. Section 4312 of the Business and Professions Code is amended to read:

4312. (a) The board may cancel the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) In the event that the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer is cancelled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a wholesaler, pharmacy, or veterinary food-animal drug retailer notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek

and obtain an order from the superior court in the county in which the wholesaler, pharmacy, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, pharmacy, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, pharmacy, or veterinary food-animal drug retailer.

(d) In the event that the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, ‘‘closed’’ means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

SEC. 14. Section 4314 is added to the Business and Professions Code, to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of this chapter or regulations adopted pursuant to this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine .

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

SEC. 15. Section 4315 is added to the Business and Professions Code, to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

SEC. 16. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).

(i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(*l*) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

SEC. 17. Section 4403 of the Business and Professions Code is amended to read:

4403. The board shall not reissue or renew any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.

SEC. 18. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section

17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

Attachment B

AMENDED IN ASSEMBLY JULY 8, 2003

AMENDED IN ASSEMBLY JUNE 26, 2003

AMENDED IN SENATE JUNE 2, 2003

AMENDED IN SENATE MAY 14, 2003

AMENDED IN SENATE APRIL 8, 2003

SENATE BILL No. 151

Introduced by Senator Burton
(Coauthors: Senators Aanestad, Kuehl, and Torlakson)
(Coauthors: Assembly Members Berg, Canciamilla, Cohn, Dymally, Hancock, Jerome Horton, Koretz, Leno, Lieber, Longville, and Lowenthal)

February 7, 2003

An act to amend Sections 11165.1 and 11166 of, to amend and repeal Sections ~~11159.2,~~ 11162, 11168, and 11169 of, to amend, repeal, and add Sections *11159.2,* 11161, 11164, 11165, 11167, 11167.5, and 11190 of, to add Sections 11029.5, 11161.5, 11161.7, 11162.1, and 11162.6 to, and to add, repeal, and add Section 11164.1 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 151, as amended, Burton. Controlled substances: Schedule II.

Existing law provides that no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless it complies with specified requirements, one of which is that prescriptions for Schedule II controlled substances shall be prepared on triplicate prescription blanks issued by the Department

of Justice. Existing law also provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program, as specified. The CURES program is scheduled to become inoperative on July 1, 2008, and repealed on January 1, 2009. Existing law provides that a violation of any of these provisions is generally a misdemeanor.

This bill would, on and after July 1, 2004, eliminate the triplicate prescription requirement for Schedule II controlled substances and would, on and after January 1, 2005, require prescribers of Schedule II controlled substances to meet the same prescription requirements imposed with respect to other prescribable controlled substances, as specified. The bill would, on and after January 1, 2005, require prescriptions for any controlled substance to be issued on controlled substance prescription forms obtained from a security printer approved by the Board of Pharmacy, as specified. Between July 1, 2004, and January 1, 2005, these prescriptions would be permitted using either the triplicate form or the security forms. The bill would make the CURES program applicable to Schedule III drugs if there is adequate funding and would also provide for the indefinite continuation of the CURES program by deleting its repeal date. The bill would make it a crime to counterfeit a controlled substance prescription; knowingly possess a counterfeited controlled substance prescription; or obtain under false pretenses, or fraudulently produce, a controlled substance prescription, as specified. By creating new crimes, the bill would impose a state-mandated local program.

The bill would also revise provisions relating to electronically transmitted prescriptions and would add provisions authorizing pharmacies to dispense certain prescriptions from out-of-state prescribers, as specified. The bill would make conforming changes to related provisions.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature in enacting this act to do the following:

(a) Increase patient access to appropriate pain medication and prevent the diversion of controlled substances for illicit use.

(b) Provide that the forms required by the act for controlled substance prescriptions may be used to prescribe any prescription drug or device.

SEC. 2. Section 11029.5 is added to the Health and Safety Code, to read:

11029.5. ''Security printer'' means a person approved to produce controlled substance prescription forms pursuant to Section 11161.5.

SEC. 3. Section 11159.2 of the Health and Safety Code is amended to read:

11159.2. (a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall not be subject to Section 11164.

(b) (1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. The signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed, as provided in paragraph (3) of subdivision (b) of Section 11164, and shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber, as provided in paragraph (2) of subdivision (b) of Section 11164.

(3) The prescription shall also indicate that the prescriber has certified that the patient is terminally ill by the words ''11159.2 exemption.''

(c) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (3) of subdivision (b), provided that he or she has

personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(d) For purposes of this section, ''terminally ill'' means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(e) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 3.5. Section 11159.2 is added to the Health and Safety Code, to read:

11159.2. (a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, 'terminally ill' means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(d) This section shall become operative on July 1, 2004.

SEC. 4. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate unless a practitioner orally, electronically, or in writing requests a larger amount, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable. Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor.

(b) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks in the practitioner's possession at a time set in the order and shall direct the Department of Justice to withhold prescription blanks from the practitioner. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (c) and (f) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(c) The order provided by subdivision (b) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(d) The defendant may elect to challenge the order issued under subdivision (b) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (c) and any other evidence otherwise admissible at the preliminary examination.

(e) If the practitioner has not moved to vacate the order issued under subdivision (b) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (b) shall be vacated.

(f) Notwithstanding subdivision (e), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (b).

(g) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 5. Section 11161 is added to the Health and Safety Code, to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks or controlled substance prescription forms in the practitioner's possession at a time set in the order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks or controlled substance prescription forms with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on July 1, 2004.

SEC. 6. Section 11161.5 is added to the Health and Safety Code, to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy.

(b) The Board of Pharmacy may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; and all managing general partners, if any.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, or managing general partner.

(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The applicant shall also provide fingerprints, in a manner specified by the Board of Pharmacy, for the purpose of completing state and federal criminal background checks.

(c) Prior to approving a security printer application, the Board of Pharmacy shall submit a copy of the application to the Department of Justice; the Department of Justice may, within 30 calendar days of receipt of the application from the Board of Pharmacy, deny the security printer application.

(d) The Board of Pharmacy or the Department of Justice may deny a security printer application on any of the following grounds:

(1) The applicant has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The Board of Pharmacy or Department of Justice determines that the applicant has submitted an incomplete application.

(e) The Board of Pharmacy shall maintain a list of approved security printers and the Board of Pharmacy shall make this information available to prescribers and other appropriate government agencies, including the Department of Justice.

(f) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances.

(g) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer.

(h) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(i) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(j) (1) The Board of Pharmacy or the Department of Justice may revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the Board of Pharmacy or the Department of Justice revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

(k) Security printer applicants may appeal a denial or revocation by the Board of Pharmacy to the full board in a public meeting of the Board of Pharmacy.

SEC. 7. Section 11161.7 is added to the Health and Safety Code, to read:

11161.7. (a) When a prescriber's authority to prescribe controlled substances is restricted by civil, criminal, or administrative action, or by an order of the court issued pursuant to Section 11161, the law enforcement agency or licensing board that sought the restrictions shall provide the name, category of licensure, license number, and the nature of the restrictions imposed on the prescriber to security printers, the Department of Justice, and the Board of Pharmacy.

(b) The Board of Pharmacy shall make available the information required by subdivision (a) to pharmacies and security printers to prevent the dispensing of controlled substance prescriptions issued by the prescriber and the ordering of

additional controlled substance prescription forms by the restricted prescriber.

SEC. 8. Section 11162 of the Health and Safety Code is amended to read:

11162. (a) The prescription blanks shall be printed on distinctive paper, the serial number of the group being shown on each form, and each form being serially numbered. The prescription blanks shall bear the preprinted name, address, and category of professional licensure of the practitioner to whom they are issued, and the federal registry number for controlled substances.

(b) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 9. Section 11162.1 is added to the Health and Safety Code, to read:

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive ''void'' pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word ''void'' shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words ''California Security Prescription.''

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermo-chromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:

1-24
25-49
50-74
75-100
101-150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall either (A) contain a statement printed on the bottom of the prescription blank that the ''Prescription is void if more than one controlled substance prescription is written per blank'' or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the ''Prescription is void if the number of drugs prescribed is not noted.''

(9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

(10) A check box indicating the prescriber's order not to substitute.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) The designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued.

(B) The record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued

to each prescriber; the record shall be maintained in the health facility for three years.

(d) This section shall become operative on July 1, 2004.

SEC. 10. Section 11162.6 is added to the Health and Safety Code, to read:

11162.6. (a) Every person who counterfeits a controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail for not more than one year, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(b) Every person who knowingly possesses a counterfeited controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(c) Every person who attempts to obtain or obtains a controlled substance prescription form under false pretenses shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(d) Every person who fraudulently produces controlled substance prescription forms shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars ($1,000), or by both that imprisonment and fine.

(e) This section shall become operative on July 1, 2004.

SEC. 11. Section 11164 of the Health and Safety Code is amended to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance unless it complies with the requirements of this section.

(a) The signature on each prescription for a controlled substance classified in Schedule II shall be wholly written in ink in the handwriting of the prescriber upon the official prescription form issued by the Department of Justice. Each prescription shall be prepared in triplicate, signed by the prescriber, and shall contain, either typewritten or handwritten by the prescriber or his or her employee, the date, name, and address of the person for whom the controlled substance is prescribed, the name, quantity,

and strength of the controlled substance prescribed, directions for use, and the address, category of professional licensure, and the federal controlled substance registration number of the prescriber. The original and duplicate of the prescription shall be delivered to the pharmacist filling the prescription. The duplicate shall be retained by the pharmacist and the original, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state license number, the date the prescription was filled and the signature of the pharmacist, shall be transmitted to the Department of Justice at the end of the month in which the prescription was filled. Upon receipt of an incompletely prepared official prescription form of the Department of Justice, the pharmacist may enter on the face of the prescription the address of the patient. A pharmacist may fill a prescription for a controlled substance classified in Schedule II containing an error or errors, if the pharmacist notifies the prescriber of the error or errors and the prescriber approves any correction. The prescriber shall fax or mail a corrected prescription to the pharmacist within seven days of the prescription being dispensed.

(b) Each prescription for a controlled substance classified in Schedule III, IV, or V, except as authorized by subdivision (c), shall be subject to the following requirements:

(1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. With respect to prescriptions for controlled substances classified in Schedules III and IV, the signature and date shall be wholly written in ink in the handwriting of the prescriber.

(2) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber. The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand. Notwithstanding any provision in this section, the prescriber's address, telephone number, category of professional licensure, or federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(c) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be reduced to writing by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. The date of issue of the prescription and all the information required for a written prescription by subdivision (b) shall be included in the written record of the prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient if that information is readily retrievable in the pharmacy. Pursuant to authorization of the prescriber, any employee of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the employee of the prescriber transmitting the prescription.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Notwithstanding any provision of subdivisions (b) and (c), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(f) In addition to the prescriber's record required by Section 11190, any practitioner dispensing a controlled substance classified in Schedule II in accordance with subdivision (b) of Section 11158 shall prepare a written record thereof on the official forms issued by the Department of Justice, pursuant to Section 11161, and shall transmit the original to the Department of Justice in accordance with any rules that the department may adopt for completion and transmittal of the forms.

(g) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 12. Section 11164 is added to the Health and Safety Code, to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance unless it complies with the requirements of this section.

(a) (1) The signature on each prescription for a controlled substance classified in Schedule II shall be wholly written in ink in the handwriting of the prescriber upon the official prescription form issued by the Department of Justice or on a controlled substance prescription form that meets the requirements of Section 11162.1.

(2) Each prescription shall be signed by the prescriber and shall contain, either typewritten or handwritten by the prescriber or his or her agent, the date, name, and address of the person for whom the controlled substance is prescribed; the name, quantity, strength , and directions for use of the controlled substance prescribed; and the address, category of professional licensure, and federal controlled substance registration number of the prescriber.

(3) If the prescriber uses an official prescription form issued by the Department of Justice, the original and duplicate of the prescription shall be delivered to the pharmacist filling the prescription; the duplicate shall be retained by the pharmacist and the original, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state license number, the date the prescription was filled, and the signature of the pharmacist, shall be transmitted to the Department of Justice at the end of the month in which the prescription was filled.

(4) Upon receipt of an incompletely prepared official prescription form of the Department of Justice, the pharmacist may enter on the face of the prescription the address of the patient.

(5) A pharmacist may fill a prescription for a controlled substance classified in Schedule II containing an error or errors, if the pharmacist notifies the prescriber of the error or errors and the prescriber approves any correction; the prescriber shall fax or mail a corrected prescription to the pharmacist within seven days of the prescription being dispensed.

(b) Each prescription for a controlled substance classified in Schedule III, IV, or V, except as authorized by subdivision (c), shall be subject to the following requirements:

(1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. With respect to prescriptions for controlled substances classified in Schedules III and IV, the signature and date shall be written in ink in the handwriting of the prescriber.

(2) (A) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber.

(B) The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand.

(C) Notwithstanding any other provision in this section, the prescriber's address, telephone number, category of professional licensure, and federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed; if the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an agent acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(c) (1) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (b) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or

electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the hard copy record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Notwithstanding subdivisions (b) and (c), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(f) This section shall become operative on July 1, 2004, and shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 13. Section 11164 is added to the Health and Safety Code, to read:

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the person for whom the controlled substance is prescribed; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by

any other person expressly authorized by provisions of the Business and Professions Code.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(e) This section shall become operative on January 1, 2005.

SEC. 14. Section 11164.1 is added to the Health and Safety Code, to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2004, and shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 15. Section 11164.1 is added to the Health and Safety Code, to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II and Schedule III controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2005.

SEC. 16. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department

of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 17. Section 11165 is added to the Health and Safety Code, to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any

individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

SEC. 18. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II or Schedule III controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II or Schedule III controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by

a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

SEC. 19. Section 11166 of the Health and Safety Code is amended to read:

11166. No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

SEC. 20. Section 11167 of the Health and Safety Code is amended to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in the loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:

(a) The order contains all of the information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in indelible pencil or ink, and the pharmacy reduces any oral or electronic data transmission order to writing prior to actually dispensing the controlled substance.

(c) The prescriber provides a triplicate prescription, completed as provided by subdivision (a) of Section 11164, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber’s failure to do so and shall make and retain a written, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 21. Section 11167 is added to the Health and Safety Code, to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in the loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:

(a) The order contains all of the information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a triplicate prescription form or a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on July 1, 2004, and shall remain in effect until January 1, 2005, at which time it is repealed.

SEC. 22. Section 11167 is added to the Health and Safety Code, to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

(c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.

(e) This section shall become operative on January 1, 2005.

SEC. 23. Section 11167.5 of the Health and Safety Code is amended to read:

11167.5. (a) An order for a controlled substance classified in Schedule II in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care may be dispensed upon an oral or electronically transmitted prescription. Prior to filling the prescription, the pharmacist shall reduce it to writing in ink or indelible pencil in the handwriting of the pharmacist upon an official prescription form issued by the Department of Justice for that purpose. The prescriptions shall be prepared in triplicate and shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed facility or home health agency providing hospice care in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, and federal controlled substance registration number of the prescriber. The duplicate shall be retained by the pharmacist, and the triplicate shall be forwarded to the prescriber by the end of the month in which the prescription was issued. The original shall be

properly endorsed by the pharmacist with the pharmacy's state license number, the signature of the pharmacist, the name and address of the pharmacy, and the signature of the person who received the controlled substance for the licensed facility or home health agency providing hospice care and shall be forwarded by the pharmacist to the Department of Justice at the end of the month in which the prescription was filled. A skilled nursing facility, intermediate care facility, or licensed home health agency providing hospice care shall forward to the dispensing pharmacist a copy of any signed telephone order, chart order, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) For the purposes of this section, ''hospice care'' means interdisciplinary health care which is designed to alleviate the physical, emotional, social, and spiritual discomforts of an individual who is experiencing the last phases of a terminal disease and to provide supportive care for the primary care person and the family of the patient under hospice care.

(c) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 24. Section 11167.5 is added to the Health and Safety Code, to read:

11167.5. (a) An order for a controlled substance classified in Schedule II for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice may be dispensed upon an oral or electronically transmitted prescription. If the prescription is transmitted orally, the pharmacist shall, prior to filling the prescription, reduce the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy for this purpose. If the prescription is transmitted electronically, the pharmacist shall, prior to filling the prescription, produce, sign, and date a hard copy prescription. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address,

category of professional licensure, license number, and federal controlled substance registration number of the prescriber. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice. A licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) This section shall become operative on July 1, 2004.

SEC. 25. Section 11168 of the Health and Safety Code is amended to read:

11168. (a) The prescription book containing the prescriber's copies of prescriptions issued shall be retained by the prescriber which shall be preserved for three years.

(b) This section shall remain in effect only until January 1, 2008, and as of that date is repealed.

SEC. 26. Section 11169 of the Health and Safety Code is amended to read:

11169. (a) When codeine, or dihydrocodeinone or tincture opii camphorata (paregoric) is not combined with other medicinal ingredients, it shall be prescribed on the official triplicate blanks.

(b) This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 27. Section 11190 of the Health and Safety Code is amended to read:

11190. Every practitioner, other than a pharmacist, who issues a prescription, or dispenses or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(a) The name and address of the patient.

(b) The date.

(c) The character, including the name and strength, and quantity of controlled substances involved.

The prescriber's record shall show the pathology and purpose for which the prescription is issued, or the controlled substance administered, prescribed, or dispensed.

This section shall become inoperative on July 1, 2004, and, as of January 1, 2005, is repealed.

SEC. 28. Section 11190 is added to the Health and Safety Code, to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance is administered or prescribed.

(c) (1) For each prescription for a Schedule II controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) Pharmacy prescription number, license number, and federal controlled substance registration number.

(D) NDC (National Drug Code) number of the controlled substance dispensed.

(E) Quantity of the controlled substance dispensed.

(F) ICD-9 (diagnosis code), if available.

(G) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in either hard copy or electronic form.

(d) This section shall become operative on July 1, 2004, and shall remain in effect only until January 1, 2005, and as of that date is repealed.

SEC. 29. Section 11190 is added to the Health and Safety Code, to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) Pharmacy prescription number, license number, and federal controlled substance registration number.

(D) NDC (National Drug Code) number of the controlled substance dispensed.

(E) Quantity of the controlled substance dispensed.

(F) ICD-9 (diagnosis code), if available.

(G) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in either hard copy or electronic form.

(d) This section shall become operative on January 1, 2005.

SEC. 30. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution

because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment C

Legislation and Regulation

Goal

Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Implementation Responsibility

Legislation and Regulation Committee and Staff

Strategic Objectives	Timeline
1. Secure the passage of legislation extending the board's sunset date. ▪ Submitted the Sunset Review Report to the Joint Legislative Sunset Review Committee (JLSRC) on September 3, 2002. ▪ Provided testimony before the JLSRC on November 19, 2002. ▪ The JLSRC voted to extend the board for four years on April 7, 2003. ▪ SB 361 (Figueroa) passed the Senate on May 22, 2003.	September 2003
2. Revise the Notice to Consumers required by 16 CCR section 1707.2 ▪ Regulation approved by OAL on August 8, 2002.	September 2002
3. Promulgate a regulation protecting financial records submitted to the board as part of a site license application as confidential documents.	July 2003
4. Promulgate a regulation to permit pharmacies to depot drugs for delivery to patients at non-pharmacy locations where the patient receives health care services. ▪ Notice of Proposed Action published August 2, 2002. ▪ Board approved the regulation at the October 2002 board meeting. ▪ Rulemaking file submitted for review by the Department of Consumer Affairs, December 2002.	July 2003

Strategic Objectives	Timeline
▪ Rulemaking file was approved by OAL and was effective on March 12, 2003.	
5. Promulgate expanded citation and fine regulations permitting citation and fine for violations of the Confidentiality of Medical Information Act and for Internet violations.	August 2002
▪ Rulemaking file submitted to OAL on September 13, 2002.	
▪ Rulemaking approved by the Office of Administrative Law on October 23, 2002.	
6. Revise regulations concerning electronic prescribing to conform to AB 2240, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity.	July 2003
7. Initiate regulations to specify the procedure for foreign pharmacy graduates who cannot obtain transcripts to become eligible to take the pharmacist licensure examinations.	July 2003
▪ Rulemaking notice published on August 2, 2002.	
▪ Board approved the regulation at the October 2002 board meeting.	
▪ Rulemaking file submitted for review by the Department of Consumer Affairs, December 2002.	
▪ Rulemaking file was approved by OAL and became effective March 13, 2003.	
8. Conform board regulations regarding partial filling of Schedule II substances with statutory changes to Schedule II prescription requirements.	July 2003
▪ Notice of Proposed Action published August 2, 2002.	
▪ Board approved the regulation at the October 2002 board meeting.	
▪ Rulemaking file submitted for review by the Department of Consumer Affairs, December 2002.	
▪ Rulemaking file was approved by OAL and was effective on March 12, 2003.	

Strategic Objectives	Timeline
9. Promulgate a regulation for standards for sterile compounding of drug products. ▪ Notice of Proposed Action published August 30, 2002. ▪ Regulation hearing held at the October 2002 board meeting. ▪ Regulation workshop on revised standards held on December 5, 2002. ▪ Revised regulation noticed on February 21, 2003 and the 45-day comment period closed on April 7, 2003. ▪ Board adopted regulation on April 29, 2003 ▪ 15-day notice ended June 19, 2003.	January 2003
10. Revise regulations to make technical corrections required by recent legislation. ▪ Section 100 rulemaking was approved in September 2002.	January 2003
11. Promulgate a regulation recognizing continuing education credits for courses approved by other health care licensing boards. Informational hearing conducted on September 24, 2002. ▪ Rulemaking notice was published on October 31, 2002. ▪ Board adopted the regulation at the January 22, 2003 board meeting. ▪ Rulemaking file submitted to DCA for approval.	March 2003
12. Hold two public meetings annually to develop board proposals for legislation and regulation changes, and to recommend policy positions on introduced legislation. ▪ Public meeting held on October 24, 2002 in conjunction with quarterly board meeting. ▪ Public meeting held on March 27, 2003 in the board's Sacramento office.	October 2002 and March 2003

Ongoing Objectives

13. Promote the board's policy positions on pending legislation.

The board supported the following legislation in 2002:

AB 269 (Correa) Support
AB 2045 (Matthews) Support
AB 2191 (Migden) Support
AB 2935 (Strom-Martin) Support
SB 1558 (Figueroa) Support
SB 1750 (Speier) Support If Amended
SB 1785 (Vasconcellos) Support
SB 2018 (Figueroa) Support
SB 2026 (Senate Business and Professions Committee) Support

The board supported the following legislation in 2003:

AB 261 (Maddox) Support
AB 746 (Matthews) Support
AB 1363 (Berg) Support
AB 1460 (Nation) Support
SB 151 (Burton) Support
SB 175 (Kuehl) Support
SB 361 (Figueroa) Support
SB 393 (Aasnestead) Support
SB 490 (Alpert) Support
SB 774 (Vasconcellos) Support

The board opposed the following legislation in 2003:

SB 506 (Sher) Oppose
SB 545 (Speier) Oppose

14. Advocate the board's role in promoting public protection regarding pharmacists' care and dispensing of dangerous drugs and devices.

- Board members participated in medication safety forum on September 26, 2002.
- Staff made presentation to UCSF pharmacy students on the board's role and contemporary issues in pharmacy law on February 18, 2003.
- Board president moderated discussion on adopting the NAPLEX at UCSF School of Pharmacy.

15. Pursue legislation and regulations that provide consumer protection while minimizing intrusion on the marketplace, to the extent possible.

    - Sponsored AB 2655 (Matthews) to extend CURES for five years and make profile data available to practitioners.
    - AB 2655 (Matthews) signed by the Governor on August 31, 2002.
    - Sponsored provisions in SB 361 to provide the board will three enforcement tools (order of correction, letter of admonishment, mandatory continuing education).

16. Undertake continual review of statutes and regulations to assure they reflect actual pharmacy practice and provide a consumer protection focus.

    - Section 100 update of Title 16, Division 17 approved September 2002.
    - Sponsored provisions in the annual omnibus bill (SB 2026) to update the Pharmacy Law and the California Uniform Controlled Substances Act.
    - Sponsored provisions in the board's sunset review bill (SB 361) to make a number of technical corrections to the Pharmacy Law.

17. Promote and advocate legislative or regulatory changes to keep pharmacy requirements current and consistent with the board's strategic purpose.

    - Sponsored provisions in SB 361 to revise the qualifications for becoming licensed as a pharmacy technician.

18. Participate in local, state and national forums to advocate the public interest in emerging policy and regulatory areas regarding pharmacists' care and the dispensing of dangerous drugs and devices.

    - Staff participated in the annual forum for regulators and educators at the NACDS Pharmacy Technology Conference on September 10, 2002.

    - Staff presented the proposed sterile compounding standards and quality assurance program regulations to the National Home Infusion Association on September 17, 2002.

    - Staff and Board Members made a presentation regarding the quality assurance program regulation to the CPhA Western Pharmacy Education Faire on September 27, 2002.

    - The board staffed an information booth at the CPhA Western Pharmacy Education Faire.

    - Staff made a presentation to the Los Angeles District Attorney on the CURES program October 4, 2002.

    - The board staffed an information booth at the CSHP Seminar in Anaheim October 3-6.

    - The Board President addressed the National Association of Boards of Pharmacy mid-year conference in November 2002 regarding quality assurance.

    - The board president participated in the National Association of Boards of Pharmacy HIPAA task force.

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Attachment D

MEETING MINUTES
LEGISLATION AND REGULATION COMMITTEE
DATE: JULY 11, 2003
LOCATION: TELECONFERENCE

BOARD MEMBERS PRESENT:

ANDREA ZINDER, CHAIR
DAVE FONG

BOARD STAFF PRESENT:

VIRGINIA HEROLD
PAUL RICHES

The meeting was convened at 8:40 a.m.

Regulations Update

The committee was provided with an update on the status of pending regulation packages as follows:

Section 1732.2 – Continuing Education
Status: Pending OAL review

Section 1751 – Sterile Compounding
Status: Awaiting publication of a 15-day notice

Section 1775 – Citation and Fine
Status: Pending DCA review

The committee directed staff to prepare draft language for all pending rulemaking proposals for an informational hearing on September 11, 2003 in Sacramento.

Sunset Review

Senate Bill 361 (Figueroa) is the board's sunset review legislation. The bill contains the recommendations from the Joint Legislative Sunset Review Committee that require statutory changes including:

Adoption of NAPLEX
Add two public members to the board
Permit non-pharmacists to be board inspectors
Revision of pharmacy technician qualifications

The bill also contains the board's omnibus items for 2003.

The bill will be heard in the Assembly Business and Professions Committee on Wednesday, July 9, 2003. The bill has no opposition at this time and is expected to be signed by the Governor. The bill was recently amended to require periodic evaluation of the NAPLEX and require that one pharmacist board member be a union member. These amendments removed opposition from the United Food and Commercial Workers.

Legislation Update

The committee was provided an update on the status of pending legislation as follows:

AB 261 (Maddox) Increases penalties for operating a "backroom pharmacy."
Board Position: **Support**
Status: Dead

AB 746 (Matthews) Requires the board to revoke a license after a second conviction for Medi-Cal fraud.
Board Position: **Support**
Status: Senate Business and Professions Committee

AB 1363 (Berg) Establishes requirements for needle exchange programs.
Board Position: **Support**
Status: Two-year bill

AB 1460 (Nation) Permits pharmacists to perform CLIA waived tests to monitor drug therapy.
Board Position: **Support**
Status: Two-year bill

SB 151 (Burton) Eliminates the triplicate requirement for Schedule II prescriptions and requires a tamper resistant prescribing pad for all controlled substance prescriptions. Adds Schedule III drugs to CURES.
Board Position: **Support**
Status: Assembly Appropriations Committee

SB 175 (Kuehl) Adds veterinary drugs to the definition of dangerous drugs.
Board Position: **Support**
Status: Assembly Appropriations Committee

SB 393 (Aanestad) Permits "tech check tech" in hospitals.
Board Position: **Support if Amended**
Status: Two-year bill

SB 490 (Alpert) Establishes a statewide protocol for pharmacists dispensing emergency contraception.
Board Position: **Support**
Status: Assembly Health Committee

SB 506 (Sher) Requires the board to track wholesale distribution of antibiotic drugs.
Board Position: **Oppose**
Status: Two-year bill

SB 545 (Speier) Limits the nature of the consultation and the fee that may be charged by pharmacists dispensing emergency contraception. Eliminates the training requirement for a pharmacist to dispense emergency contraception.
Board Position: **None**
Status: Assembly Health Committee

SB 774 (Vasconcellos) Eliminates the prescription requirement for hypodermic needles and syringes.
Board Position: **Support**
Status: Assembly Health Committee

Bills of Interest

AB 57 (Bates) Places MDMA into Schedule II.
Status: Assembly Inactive File

AB 186 (Correa) Makes technical changes to the Pharmacy Law relating to optometrists.
Status: Senate Business and Professions Committee

AB 521 (Diaz) Requires pharmacists to notify patients of harmful drug interactions.
Status: Senate Business and Professions Committee

AB 1196 (Montanez) Permits nurse practitioners to order Schedule II drugs.
Status: Senate Business and Professions Committee

SB 292 (Speier) Requires prescription labels to have a description of the drug.
Status: Assembly Health Committee

Future Meetings.

The committee agreed to conduct its next meeting on September 11, 2003 at 10 a.m.

Adjournment

The committee adjourned at 9:45 a.m.